

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES: <i>Identified in Exhibit A</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE
EXPERT TESTIMONY OF MICHAEL KARRAM, MD**

Plaintiffs in the above-captioned consolidated cases respectfully move this Court to exclude the testimony of Michael Karram, M.D., a proffered expert witness for the Defendants, regarding Ethicon's TVT and TVT-O mesh products. Dr. Karram does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. Additionally, Dr. Karram has not followed a reliable methodology to reach many of his opinions.

Specifically, Dr. Karram offers opinions regarding the *adequacy* of Ethicon's warnings in its TVT and TVT-O IFUs and patient brochures, but he lacks the necessary qualifications to testify regarding the adequacy of Ethicon's warnings. Despite the Court consistently excluding state-of-mind testimony, Dr. Karram also seeks to testify as to the state-of-mind of doctors, including what he erroneously believes *all* doctors know about the risks of these products. Finally, Dr. Karram seeks to testify as to the biomechanical aspects of the mesh used in these devices, yet he has not followed any reliable methodology and admits he is not qualified in these areas. Accordingly, Plaintiffs respectfully request that the Court exclude Dr. Karram's opinions and testimony.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

To meet the standard of reliability, the testimony “must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995). The function of the Court is to act as a gatekeeper when it comes to expert testimony: “[E]xpert witnesses have the potential to be both powerful and quite misleading[;]” and it is incumbent upon the Court to “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993)).

Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because “*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996). The

court has considerable discretion in determining an expert witness' testimony is admissible and whether the expert should be admitted or excluded. "[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152). Additionally, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).

ARGUMENT

The Court should prohibit Dr. Karram, a urogynecologist designated as a Defense expert, from presenting a number of opinions about the TVT and TVT-O devices because he is unqualified and has not followed any reliable methodology.

I. DR. KARRAM'S OPINIONS REGARDING THE ADEQUACY OF ETHICON'S WARNINGS SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED TO RENDER THESE OPINIONS AND HE FOLLOWED AN UNRELIABLE METHODOLOGY.

Dr. Karram's opinions that Ethicon provided *adequate* warnings in its TVT and TVT-O IFUs and patient brochures should be excluded. First, Dr. Karram is not qualified to offer opinions regarding these matters and admits as much. Second, Dr. Karram did not employ a reliable methodology to reach these opinions, in part, because he has not reviewed the applicable regulatory or internal Ethicon requirements for warnings. Karram dep. 6/28/16 58:12-59:14; 107:8-10 (attached as Exhibit B). In fact, based on Dr. Karram's misunderstanding of warning requirements, he does not think a manufacturer has to warn about any of the risks at issue here. *See Expert Report of Michael Karram, M.D.*, June 2, 2016 (attached as Exhibit C) ("*Report*") at 22 ("Although I am not a regulatory expert, I have reviewed 21 C.F.R. 801.109(c), which provides for the omission of risk information..."). Accordingly, his opinions related to the adequacy of Ethicon's warnings should be excluded in their entirety.

On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire*, 526 U.S. at 156). Only after this criterion related to qualifications is satisfied does the *Daubert* standard apply. Dr. Karram does not possess the necessary qualifications to opine about the adequacy of the warnings contained in Ethicon’s IFUs.

Dr. Karram readily admits he is “not a regulatory expert...” *Report* at 22 (“Although I am not a regulatory expert...”); Karram dep. 3/29/16 50:19-51:4 (attached as Exhibit D) (“Q. You don't hold yourself out as an expert witness in FDA regulations related to medical devices, do you? A. No.”). As the Court has consistently held, an “expert must possess additional expertise to offer testimony about what information should or should not be included in an IFU.” *See e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 10 (S.D. W. Va. Aug. 31, 2016) (Doc. No. 2701) (Memorandum Opinion and Order – *Daubert* Motion re: Brian J. Flynn, M.D.) (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202 at *14 (S.D. W. Va. Feb. 7, 2015)). Dr. Karram does not possess such expertise.

Further, Dr. Karram has not reviewed the relevant regulations regarding warning requirements. Dr. Karram states that one of the bases for his opinions regarding the adequacy of Ethicon’s warnings is his review of 21 C.F.R. 801.109(c). *Report* at 22; Karram dep. 6/28/16 58:7-11. Specifically, Dr. Karram proposes that 21 C.F.R. 109 somehow excuses Ethicon from warning about the risks associated with these devices. However, when asked how he decided Section 109 is applicable here, Dr. Karram testified that he did not actually read the entire regulation. Karram dep. 6/28/16 58:12-59:13 (“I did not read the whole thing.”). Dr. Karram’s warnings opinions are simply based on his own personal belief and not any reliable objective standard.

Dr. Karram also opines that Ethicon provided adequate warnings in its patient brochures. However, Dr. Karram never discussed any of the actual warnings in his Report. Additionally, Dr. Karram never reviewed any of the regulatory requirements for patient labeling. Karram dep. 6/28/16 106:23-107:4 (“No. I didn’t even know there was regulation for patient labeling.”). Likewise, Dr. Karram did not review any of Ethicon’s internal standards regarding patient labeling. Karram dep. 6/28/16 107:5-7. Like his product labeling opinions, his opinions regarding the adequacy of patient labeling have no reliable basis and are not the product of a reliable methodology.

Dr. Karram is not qualified to offer opinions about the adequacy of Ethicon’s warning. Dr. Karram’s opinions that Ethicon provided adequate warnings in the IFUs and patient labeling are not based on any reliable methodology because he has not reviewed the relevant standards and does not possess the necessary qualifications. Accordingly, these opinions should be excluded.

II. DR. KARRAM SHOULD NOT BE ALLOWED TO TESTIFY AS TO THE STATE-OF-MIND OF OTHER DOCTORS, SUCH AS WHAT HE ERRONEOUSLY THINKS “ALL SURGEONS KNOW.”

Dr. Karram’s opinions regarding what “all surgeons know” or what is “commonly known” should be excluded. The Court has “consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury’s fact finding duties.” *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 7 (S.D. W. Va. Sept. 2, 2016) (Doc. No. 2727) (Memorandum Opinion and Order – *Daubert* Motion re: Michael Karram, M.D.). Additionally, Dr. Karram has not followed any reliable methodology to reach these opinions, and these opinions should be excluded.

Dr. Karram repeatedly makes broad, overarching statements such as, “It is common knowledge to pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ

prolapse ... can potentially cause complications ...” *Report* at 20, and “[T]he actual surgical risks and complications ... are commonly known to pelvic floor surgeons.” *Report* at 22. Dr. Karram admits not all doctors have his level of knowledge regarding Ethicon’s mesh devices. However, even if all doctors had his level of knowledge, he cannot provide any reliable basis for his proposition that this would excuse Ethicon from warning about the risks associated with Ethicon’s mesh implants.

Dr. Karram has worked as a consultant for Ethicon which has afforded him opportunity to learn extensive information about these products. Of course, not all doctors are similarly situated because not all doctors worked for Ethicon and were instructed on these products. He admitted that not all doctors have time to review all the literature and that some doctors are not as knowledgeable about the medical literature regarding Ethicon’s mesh devices. Karram dep. 6/28/16 30:1-10; 112:17-21. Further, Dr. Karram testified he was more knowledgeable as compared to other doctors about the medical literature regarding mesh devices. Karram dep. 6/28/16 30:11-21; 112:17-113:4.

Dr. Karram acknowledged that he has no evidence or scientific basis for personal opinions regarding the “general knowledge” of all surgeons. Karram dep. 6/28/16 112:8-11. Dr. Karram testified that he has not undertaken any attempt to survey or poll other doctors as to what they commonly know. Karram dep. 6/28/16 112:14-16. Instead, Dr. Karram has acknowledged that many of the organizations he relied upon, such as ACOG and AUGS, have stated that some doctors needed more information regarding complications associated with the mesh devices. Karram dep. 6/28/16 72:23-73:20.

Dr. Karram has not followed any reliable methodology to reach his opinions about what is common knowledge to all surgeons and instead is simply guessing. More importantly, such

testimony is an inappropriate subject for expert testimony because it would usurp the jury's fact finding duties. As such, Dr. Karram's opinions regarding the state-of-mind of surgeons and patients should be excluded.

III. DR. KARRAM'S OPINIONS REGARDING THE BIOMECHANICAL ASPECTS OF THE MESH ARE BASED ON AN UNRELIABLE METHODOLOGY.

Dr. Karram's opinions regarding the biomechanical design of the mesh should be excluded because he concedes he is not qualified in these areas and has not followed any reliable methodology. Dr. Karram opines that the specific mesh used in the TVT and TVT-O products is safe for permanent implant. However, Dr. Karram admits he is not an expert regarding the biomechanical properties of mesh. Expert testimony regarding the biomechanical aspects of the mesh should be left to experts who are adequately qualified in these areas. Dr. Karram is not so qualified, and his opinions here should be excluded.

Dr. Karram readily admits he is not an expert in these areas. He specifically testified:

- Q. You're not an expert in biomaterials; is that correct?
- A. No, that's correct.
- Q. You're not an expert in pathology?
- A. I would consider myself not an expert in pathology.

Karram 3/29/16 dep. 51:2-7. Dr. Karram further admits he is not a biomechanical engineer and would defer to a biomechanical expert regarding the specific construction of the mesh. Karram dep. 6/28/16 53:9-17.

Based on his limited understanding of these matters, Dr. Karram acknowledges there are many differences between the mesh used in Ethicon's TVT, TVT-O, and Prolift devices, such as a different pore size and different weight. Karram dep. 6/28/16 49:14-50:12. However, Dr. Karram admits he does not know the clinical impacts of these biomechanical differences. Karram dep. 6/28/16 53:18-54:2.

Dr. Karram has not followed a reliable methodology regarding the safety of the specific mesh used in these products, because he does not even understand the biomechanical differences in the mesh. Dr. Karram does not provide any scientific expertise to the jury regarding these matters. He should not be allowed to testify as to the safety of the mesh design if he cannot explain the clinical impacts regarding the mesh design.

Similar to many other opinions offered by Dr. Karram, he does not possess the qualifications nor did he undertake the appropriate review to present these opinions to a jury. The opinions of Dr. Karram related to the biomechanical properties of mesh should be excluded.

CONCLUSION

Dr. Karram does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. Additionally, the methodology employed by Dr. Karram in reaching his opinions does not satisfy the requirements for expert witness testimony as set forth in Rule 702 and under the *Daubert* standard. For the reasons stated above, Plaintiffs respectfully request this Court exclude Dr. Karram's opinions.

Respectfully submitted this 19th September, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the list of participants registered to receive service in this MDL.

/s/ Jenelle Cox